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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,381	12/02/2003	Frida Ryttsen	59664 CIP (47137)	5635
21874	7590	12/14/2006	EXAMINER	
EDWARDS & ANGELL, LLP P.O. BOX 55874 BOSTON, MA 02205			KETTER, JAMES S	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 12/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/726,381

Applicant(s)

RYTTSEN ET AL.

Examiner

James S. Ketter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 September 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-221 is/are pending in the application.
- 4a) Of the above claim(s) 136-221 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☒ Claim(s) See Continuation Sheet is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/15/05</u> . | 6) <input type="checkbox"/> Other: _____  |

Continuation of Disposition of Claims: Claims rejected are 1-7, 10-18, 20-37, 39-41, 43, 46, 50, 51, 53-56, 59-64, 70, 71, 74-78, 85, 88, 89, 95, 97-103, 107, 114, 115 and 119-123.  
Continuation of Disposition of Claims: Claims objected to are 8,9,19,38,42,44,45,47-49,52,57,58,65-69,72,73,79-84,86,87,90-94,96,104-106,108-113,116-118 and 124-135.

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Applicant's election with traverse of Group I, claims 1-135 in the reply filed on 28 September 2006 is acknowledged. The traversal is on the ground(s) that the invention relates to a single inventive concept and thus there would be no burden to search all of the Groups together. This is not found persuasive because, for reasons set forth in the restriction requirement, the inventions are distinct and would pose a burden on the Office were all to be searched together. The presence of a "single inventive concept" does not necessarily render one invention obvious over another.

The requirement is still deemed proper and is therefore made FINAL.

Claims 136-221 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 28 September 2006.

Claims 8, 9, 19, 38, 42, 44, 45, 47-49, 52, 57, 58, 65-69, 72, 73, 79-84, 86, 87, 90-94, 96, 104-106, 108-113, 116-118 and 124-135 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection

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is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 6, 7, 10-17 and 20-28 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7,109,034. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are generic to all that is encompassed in the patented claim, i.e., the instant claims are anticipated by the patented claim.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 10, 12-14, 16-18, 22, 29-31, 35-37, 39, 40, 54-56, 60-62, 64, 70, 71, 74-78, 85, 88, 89, 95, 97-103, 107, 114, 115, 119-123 are rejected under 35 U.S.C. 102(b) as being anticipated by Holmes (A, newly cited).

The instant claims are drawn to a tip-electrode comprising, in claim 1, a housing defining a lumen and an electrically conducting surface to be coupled to a voltage or current generator. Claim 2 specifies that the end facing the target has an opening. Claim 3 specifies that the lumen comprises an electrically conductive medium. Claim 4 specifies a tapered end. Claim 10 specifies that the electrically conductive medium of claim 1 is a liquid. Claim 12 specifies that the electrically conductive medium of claim 1 comprises an agent for delivery to a target. Claim 13 specifies that the housing is made of, among others, metal. Claim 14 specifies that the end facing the target has an opening. Claims 16 and 17 specify uniform inner and outer diameters. Claim 18 specifies that the electrode is less than 10 cm. Claim 22 specifies an opening of 5000 microns (5 mm) or less. Claim 29 is drawn to an electrode plate having a mounting point for a tip electrode, with claim 30 specifying that the mounting point allows vertical flexibility, and with claim 31 specifying multiple points for receiving a tip electrode. Claims 35-37 specify that there are points for interfacing with a voltage or current generator, or fluid delivery device, or that there is a conducting and an insulating layer. Claim 39 recites that the mounting point is an aperture, and 40 recites that the tip electrode is thus present. Claim 54 is a kit with a tip electrode as in claim 1 and a container holding a target. Claim 55 is drawn to a kit comprising the electrode plate of claim 29 and a tip electrode, further specifies by claim 56 as having a container for a target, claim 60 as having a counter electrode, claim 61 as having an electrically conductive medium, claim 62 as comprising an agent, or claim 64 as comprising a container containing a target. Claim 70 is drawn to a tip electrode comprising a conducting surface in contact with an electrode plate and a housing defining a lumen with an opening facing toward a target, wherein the electrode plate can be connected to a pulse generator. Claim 71 specifies that

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the target is present. Claim 74 specifies that a counter electrode is present. Claim 75 specifies that an electrically conductive medium is present in the electrode, further specified in claim 76 as comprising an agent. Claim 77 specifies that a mechanism for delivery of fluid to the electrode is present, more narrowly specified as a pump in claim 78. Claim 85 specifies detachability of the electrode from the plate. Claim 88 recites that the electrode comprises an electrically conductive medium. Claim 89 specifies a tapered end to the electrode. Claim 95 recites that the electrically conductive medium is a liquid, further specified to contain an agent in claim 97. Claim 98 specifies that the housing is made of, among others, metal. Claim 99 recites that the end distal to the target comprises an opening for receiving the electrically conductive medium. Claim 100 recites that a counter electrode surface is present. Claim 101 and 102 specify that the inner and outer diameters of the housing are, among others, of uniform diameter. Claim 103 specifies that the electrode is less than 10 cm. Claim 107 specifies an opening of 5000 microns (5 mm) or less. Claim 114 specifies that the mounting plate comprises at least one mounting point permitting vertical flexibility of the electrode, whereas claim 115 specifies a plurality of such mounting points. Claims 119 and 120 specify that there are points for interfacing with a voltage or current generator, or fluid delivery device. Claim 121 recites that there is a conducting and an insulating layer. Claim 122 recites that the electrode plate comprises a later which acts as a counter electrode. Claim 123 recites that a mounting point for the electrode comprises an aperture.

Holmes teaches, e.g., at figure 1, a syringe with a metal syringe needle which, when the plunger is pressed, is filled with and conducts an electrolytic fluid. The target to which this fluid is delivered, which comprises electrolytes as the agent, is the battery. The bevel at the end of the

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needle represents a tapered region. The needle could inherently be electrified by a power source, as it is metallic. At column 3, first full paragraph, part 60 is described as a syringe needle, and Figure 1 shows that the needle has straight sides, i.e., a uniform diameter. Figure 1 also shows part 30, which is a metallic disk which has an insulating layer (32), a structure for receiving, holding and allowing vertical movement of the needle (34, 36 and 50) which serves as the mounting point. Multiple needles or insertions through this structure are not excluded, and are thus inherent. It is taught, e.g., in the Abstract, that an electrolytic fluid is injected through the needle. This serves as the electrically conductive liquid, wherein the electrolytes within serve as the recited agents. The battery within the container (12 or 44) serves as the target. The opposite electrode of the battery or the outside of the can would serve as the counter electrode.

Claims 29-37, 39-41, 43, 46, 50, 51, 53, 55, 56, 59, 60 and 62-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Korenstein et al. (WO 95/23211, cited in IDS filed 15 September 2005).

Claim 29 is drawn to an electrode plate having a mounting point for a tip electrode, with claim 30 specifying that the mounting point allows vertical flexibility, and with claim 31 specifying multiple points for receiving a tip electrode. Claim 32 specifies a linear array of mounting points, more narrowly as a two dimensional array in claims 33 and 34. Claims 35-37 specify that there are points for interfacing with a voltage or current generator, or fluid delivery device, or that there is a conducting and an insulating layer. Claim 39 recites that the mounting point is an aperture, and 40 recites that the tip electrode is thus present. Claim 41 recites that a



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plurality of tip electrodes are mounted to the plate. Claim 43 is drawn to a tip electrode plate comprising a substantially planar plate with at least one non-planar element present, with the end of the non-planar element having an opening, the element forming a lumen. Claim 46 specifies that there is a rod, wire or filament comprised at the base of the lumen. Claim 50 specifies that there is a reservoir comprising a conductive medium, further specified in claim 51 as comprising an agent. Claim 53 further specifies this for claim 43. Claim 55 is drawn to a kit comprising the electrode plate of claim 29 and a tip electrode, further specified by claim 56 as having a container for a target, claim 60 as having a counter electrode, claim 62 as comprising an agent, claim 63 as comprising at least one cell, or claim 64 as comprising a container containing a target.

Korenstein et al. teaches, e.g., in Figures 3a and 3B, a device having an electrode plate (36) which has a two-dimensional array of tube-like non-planar extensions which extend from one surface, which thus form lumens, which lumens permit the passage of tip-electrodes and which hold and align them in an array, permitting vertical movement and withdrawal from the target, which is held in container 24. At page 12, second full paragraph, it is taught that a conductive gel may be held in part 42 for electrical contact with the needle electrodes. It is generally taught, e.g., in the Abstract, that macromolecules may be targeted into cells or tissue by the disclosed methods and apparatus. Such macromolecules represent agents.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 34 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 34, and therefore claim 41 which depends therefrom, recites “an industry standard microtiter plate.” However, this recitation renders unclear the metes and bounds of the claims, as the phrase is recited to specify the spacing of the mounting points, and the term “industry standard” does not have a clear definition in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James S. Ketter whose telephone number is 571-272-0770. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Remy Yucel can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JSK  
10 December 2006



JAMES KETTER  
PRIMARY EXAMINER